May 1, 2018

Fresenius Medical Care Renal Therapies Group, LLC
Denise Oppermann
Senior Director, Regulatory Affairs
920 Winter Street
Waltham, MA 02451

Re: K173718
Trade/Device Name: Liberty Cycler Set
Regulation Number: 21 CFR§ 876.5630
Regulation Name: Peritoneal Dialysis System and Accessories
Regulatory Class: II
Product Code: FKX
Dated: March 29, 2018
Received: March 30, 2018

Dear Denise Oppermann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173718

Device Name
Liberty Cycler Set

Indications for Use *(Describe)*

The Liberty Cycler Sets are designed to operate with the Liberty Cycler to perform acute and chronic peritoneal dialysis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(K) SUMMARY

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) Summary is provided in conformance with 21 CFR §807.92.

5.1. Submitter's Information

Name:	Fresenius Medical Care Renal Therapies Group, LLC
Address:	920 Winter Street Waltham, MA 02451-1457
Phone:	(781) 699-4479
Fax:	(781) 699-9635
Contact Person:	Denise Oppermann Senior Director Regulatory Affairs – Devices
Preparation Date:	December 4, 2017

5.2. Device Name

Trade Name:	Liberty Cycler Set
Common Name:	Cycler Set
Regulation Name:	Peritoneal dialysis system and accessories
Regulatory Class:	Class II per 21 CFR §876.5630
Product Code:	FKX
Product Code Name:	System, Peritoneal, Automatic Delivery
Classification Panel:	Gastroenterology/Urology

5.3. Legally Marketed Predicate Device

The legally marketed predicate device is the Fresenius Liberty Cycler and Disposable Cycler Sets (K043363). This device has not been subject to a design related recall.

The Liberty PDx Cycler Set (K141145) is used as a reference device.

5.4. Device Description

5.4.1. Device Identification

The Liberty Cycler Set (hereinafter referred to as "Cycler Set") is available in three (3) configurations. The sets differ only in the length of the patient and drain lines or in the number of patient connectors (Table 1).

Table 1: Liberty Cycler Sets

Cycler Set Product Codes	Product Name
050-87212	Liberty Cycler Set, Two patient connectors
050-87215	Liberty Cycler Set, One patient connector
050-87216	Liberty Cycler Set, One patient connector with extended patient and drain lines

5.4.2. Device Characteristics

The Cycler Sets are single-use Class II devices designed to operate with the Liberty Cycler to perform acute and chronic peritoneal dialysis. The Cycler Sets are provided sterile and non-pyrogenic. The Cycler Sets are sterilized using ethylene oxide (EO).

5.4.3. Environment of Use

The Cycler Sets are used in both healthcare and home environments.

5.4.4. Brief Written Description of the Device

The Cycler Sets are sterile, single-use devices designed to operate with the Liberty Cycler to perform acute and chronic peritoneal dialysis. Each Cycler Set contains a cassette portion and seven (7) fluid lines. The cassette is composed of a rigid molded plastic body covered with a flexible film (membrane). The cassette contains molded features, such as fluid channels, valve domes, and pumping chambers. There are 7 fluid lines connected to the cassette body:

- One (1) drain line (yellow clamp)
- One (1) patient connection line with two (2) stay•safe® patient connectors (blue clamp)
- Five (5) Dialysate Solution Lines (with Safe-Lock® connectors):
    - One (1) heater bag (red clamp)
    - One (1) last dialysate bag/'last fill option' (green clamp)
    - Three (3) additional solution bags (white clamps)

The flow of peritoneal dialysate solution to and from the patient's peritoneal cavity is directed by interaction between the Liberty Cycler and the cassette.

5.4.5. Materials of Use

The Cycler Sets are classified as externally communicating, blood path indirect, prolonged contact (>24 hours to 30 days) duration, Class II (Category B) devices in accordance with FDA guidance, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (16 June 2016).*

The 3 Cycler Sets designed for use with the Liberty Cycler are constructed from materials identical to the predicate device with the exception of the new film.

Materials used in the manufacture of the Cycler Sets include:

- Polypropylene (PP)
- Polyvinyl chloride (PVC)
- Polycarbonate (PC)
- High-density polyethylene (HDPE)
- Acrylic polymer
- Silicone
- Thermoplastic elastomer copolymer

5.4.6. Key Performance Characteristics

The Cycler Sets are used as accessories to the Liberty Cycler. When used in conjunction with the Liberty Cycler, they provide a sterile fluid path with secure connections (stay•safe®, Safe-Lock®, and Luer lock) to alternately draw the prescribed dialysate solution to and from the patient's peritoneal cavity.

5.5. Intended Use

The Liberty Cycler Sets are intended to be used with the Liberty Cycler.

5.6. Indications for Use

The Liberty Cycler Sets are designed to operate with the Liberty Cycler to perform acute and chronic peritoneal dialysis.

5.7. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the Cycler Sets are equivalent to the predicate Liberty Cycler Set (K043363).

- Intended use
- Principle of operation
- Design characteristics

- Sterilization method, packaging, and sterility label claims

5.8. Performance Data

Testing was either conducted or leveraged to support the determination of substantial equivalence.

- Performance
  - Cycler Set fill and drain accuracy
  - Load to close tubing clamps test
  - Load to push the stay•safe patient connector test
  - Compression tests to evaluate the break-force on the cassette ports
- Structural integrity
  - Abrasion test
  - Positive and negative pressure leak test for the Cycler Set
  - Bond strength testing (Tensile test)
  - Positive pressure leak test for stay•safe patient connector and tubing clamps
  - Film seal integrity test (Endurance test)
  - Shipping and packaging test
- Biological safety (Biocompatibility)
- Maintenance of sterility
- Human Factors (HF) validation

5.8.1. Biocompatibility Testing

Testing was conducted to support the biological safety of the Cycler Sets.

- Simulated use Leachables
- Cytotoxicity, ISO Elution Method with MEM
- Sensitization, Guinea Pig Maximization
- Intracutaneous Irritation
- Material-Mediated Pyrogenicity
- Hemocompatibility, ASTM Hemolysis (Indirect) - Extract

A toxicological risk assessment was also performed.

5.8.2. Electrical Safety and Electromagnetic Compatibility (EMC)

Not applicable. The Cycler Sets do not contain electrical components.

5.8.3. Software Verification and Validation Testing

Not applicable. The Cycler Sets do not contain software.

5.8.4. Mechanical and Acoustic Testing

No mechanical or acoustic tests were performed.

5.8.5. Animal Studies

No animal studies were performed.

5.8.6. Clinical Studies

No clinical studies were performed.

5.9. Conclusion

The intended use, principle of operation, design characteristics, and sterilization method of the Liberty Cycler Sets are the same as those of the predicate device. FMCRTG concludes that within the meaning of the Medical Device Amendments Act of 1976, the Liberty Cycler Sets are safe and effective for their intended use.